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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,252	05/18/2005	Yehoshua Yeshurun	1975/48	3767

7590 11/12/2008
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EXAMINER

PATEL, PRITESH ASHOK

ART UNIT	PAPER NUMBER
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4158

MAIL DATE	DELIVERY MODE
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11/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,252	Applicant(s) YESHURUN ET AL.	
	Examiner PRITESH PATEL	Art Unit 4158	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/22/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are inadequate, please see form PTO-948 for reasons. .

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-10 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Fernandes (WO 02/47555 A2) in view of Prausnitz et al. (WO 99/64580).

Concerning claims 1, 2, and 3 Fernandes discloses a device (10.2) for transferring a substance through the surface of the skin including a substrate (26) having a first and second side (28) and a plurality of structures (30) projecting from said second side (28) (Fig 2 and pages 3, line 21 through page 4, line 3). Fernandes does

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not disclose that the structures are microstructures and that each microstructure has at least one hollow being isolated from fluid connection with said first side of said substrate and that when said microstructures are inserted part of a substance is transferred through said hollow. Prausnitz et al. discloses the use of microstructures with hollows, defined as a channel through a microstructure with one or more openings (page 6, lines 27-30). It would have been obvious to modify the structures (30) of Fernandes with microstructures with hollows as taught by Prausnitz et al. to decrease the bore size of holes left by the device in a patient's skin, increase the number of individual structures in a given area on the substrate thus improving delivery of a substance, and allow delivery of a substance directly to a patient's skin from the device. It would have further have been obvious to one of ordinary skill in the art at the time of the invention to understand that the hollows within the microstructure are only in fluid communication with the second side (28) of said substrate from which the microstructures extend as seen in Fig 2 of Fernandes or the substance would not efficiently be distributed upon site of application of device.

Concerning claims 4 and 5, Fernandes in view of Prausnitz et al. discloses the use of a medical substance and a cosmetic substance (page 4, lines 12-15 of Fernandes). It would have been obvious to one of ordinary skill in the art at the time of the invention that active ingredients from medication is a medical substance and that vitamin A and C are common ingredients in cosmetic substances for the skin.

Concerning claim 6, Fernandes in view of Prausnitz et al. discloses a rolling arrangement (32 and 26), a substrate (26), and microstructures, together making a

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microstructure rolling system being configured that a substance is transferred during rolling (Fig 10.2 of Fernandes). It would have been obvious to one of ordinary skill in the art at the time of the invention that provided that the microstructures contain hollows in fluid communication with only the second side of the substrate (28) that the modified device (10.2), the microstructure rolling system, would transfer a substance from within the microstructures through a patient's skin when said microstructure rolling system is rolled upon a patient's skin.

Concerning claim 7, Fernandes does not disclose the use of a dispensing arrangement configured to store a substance and to dispense the substance into said hollows of said microstructures. Prausnitz et al. discloses the use of a dispensing arrangement that can be attached to a substrate on an opposite side from the microstructures (page 8, lines 9-12 and page 9, lines 9-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the microstructure structure of Fernandes with a dispensing arrangement as taught by Prausnitz et al. in order to efficiently deliver a substance through the skin of a patient.

Concerning claim 8-10, Fernandes in view of Prausnitz et al. discloses a microstructure structure with a substrate having a plurality of microstructures projecting from a second side of said substrate and not in fluid communication with a first side of said substrate and at least one hollow is configured so that when on microstructure is inserted into the skin part of a substance is transferred through the skin. It would have been obvious to one of ordinary skill in the art at the time of the invention as discussed in the above disclosure.

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Concerning claims 11 and 12, Fernandes in view of Prausnitz et al. discloses a method of transferring a substance through the surface of the skin using a microstructure structure by disposing the microstructure structure onto the skin so that said substance is transferred through the skin (claims 35-37 of Prausnitz et al.) It would have been obvious to one of ordinary skill in the art that application of the substance to the microstructures would have to occur from the second side of the substrate because is the only side in fluid communication with said microstructures. It would have further been obvious to one of ordinary skill in the art that the microstructure structure to be used is embodied in the above disclosure.

Concerning claims 13-17, Fernandes in view of Prausnitz et al. discloses the use of a medical substance and a cosmetic substance as the substance. It would have been obvious to one of ordinary skill in the art at the time of the invention that a substance delivery device used on the skin may also deliver a dry substance, a gel, or a cream.

Concerning claim 18 and 19, Fernandes discloses a rolling element to which a handle (32) is mechanically connected (Fig 10.2 of Fernandes). Fernandes does not disclose a distance between the microstructures. Prausnitz et al. discloses that the microstructures are typically between 10 nm to 1mm in cross-section (page 7, line 17). It would have been obvious to one of ordinary skill in the art at the time of the invention that the microstructures on a scale from 10nm to 1mm in cross-section could be less than 1mm in distance from one another. It would also have been obvious to one of ordinary skill in the art at the time of the invention that the rolling element is the axle connecting the substrate (26) with handle (32) and that when the handle is manipulated

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to roll the microstructure system over a patient's skin, penetration occurs when proper force is applied.

Concerning claims 21 and 22, the dispensing arrangement disclosed above contains a reservoir, which is located in the axle where the substrate and handle meet, and a control structure for the dispensing arrangement is in the handle. It would have been obvious to one of ordinary skill in the art at the time of the invention as cited in the above disclosure that as the handle is manipulated to roll the microstructure over a patient's skin, a substance is directed by the dispensing arrangement control structure from the reservoir through the microstructure's hollows to dispense the substance.

Concerning claim 20, It would have been obvious to one of ordinary skill in the art to modify the microstructure system as disclosed above with a spherical rolling element to promote movement of the microstructure system in pattern other than the movement restricted to a cylindrical rolling element and the modification does not change the functionality of the device.

5. Claims 23 and 24 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Fernandes in view of Prausnitz et al. in further view of De Guzman (US 5090084).

Concerning claims 23 and 24, Fernandes in view of Prausnitz et al. discloses a microstructure system with a roller, a handle, a plurality of microstructures, and when said handle is manipulated the roller rolls in the direction directed by the handle. Fernandes in view of Prausnitz et al. does not disclose a first direction of rolling with a first depth or a second direction of rolling with a second depth and that said second depth is zero. De Guzman discloses a roller capable of rolling in one direction by way of

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a spring and pin mechanism (claim 2 of De Guzman). It would have been obvious to one of ordinary skill in the art to modify Fernandes in view of Prausnitz with a spring and pin mechanism as taught by De Guzman to limit movement of the roller in a first direction providing a first depth of penetration and a second direction in which the roller cannot move and where said second depth is zero.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/P. P./
Examiner, Art Unit 4158
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/Gary Jackson/
Supervisory Patent Examiner
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